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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,185	01/09/2001	Marina Ziche	ZICHE1	5690
7590 12/17/2003 BROWDY AND NEIMARK, P.L.L.C. 624 Ninth Street, N.W. Washington, DC 20001			EXAMINER MITRA, RITA	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/756,185	<b>Applicant(s)</b> ZICHE ET AL.	
	<b>Examiner</b> Rita Mitra	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,4,6 and 10-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4,6 and 10-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

Applicants' amendment and response to the office action dated April 22, 2003 (paper #8), filed on September 22, 2003 is acknowledged. Claims 4, 10, 13, 14, 17, 18, 21 and 22 are included in the rejection in previous office action because these claims are dependent upon rejected claims 3, 4, 11, 12, 11, 12, 20 and 20 respectively. Therefore, claims 3, 4, 6 and 10-25 are currently pending and are under examination.

### ***Response to Remarks and Arguments***

#### **Withdrawal of Rejections.**

The rejection of claims 15 and 16 under **35 U.S.C. 112, second paragraph** is withdrawn in view of Applicants' remarks on page 2.

The rejection of claims 3, 6, 19, 23-25 under **Nonstatutory Double Patenting**, is withdrawn in view of applicants' remarks at pages 4-9.

#### **Rejection under 35 USC § 112, Second Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 19 and 23 stand/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 23 are indefinite for the term "relative amount." It is not clear what is that amount which would provide synergistic results. What is that amount and relative to what?

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 6, 11, 12, 19, 20, 23-25 stand/are rejected under 35 U.S.C. 103(a) as being unpatentable over Martelli F. (WO 97/39765, October 30, 1997, Reference AB of IDS) taken with Folkman J. ("Clinical application of research on angiogenesis", Seminars in medicine of the Beth Israel Hospital, vol 333, No. 26, 1995, Reference AC of IDS).

Martelli discloses a pharmaceutical composition comprising component B as active ingredient, together with a pharmaceutically acceptable carrier (see claim 3 and also page 13). Martelli also teaches a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering an effective amount of Component B, together with a pharmaceutically acceptable carrier (see claim 4 and pages 1-2). This addresses claims 3, 11, 12 and 20 of the instant application. In view of the fact that the reference teaches

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both composition and method of treatment using Component B, it would have been obvious to and motivated one of ordinary skill in the art to have combined the teachings with those of, Folkman J.

Folkman teaches several angiogenic proteins e.g. bFGF and vEGF, whose angiogenic activity can be synergistic (see page 1757, col 2, lines 13-19). This addresses claims 3, 6, 19, 23, 24 and 25 of the instant application. Furthermore, Folkman does not teach a composition that comprises Component B as claimed in claims 3 and its dependent claims 3, 4, 6 and 10. In view of the fact that Martelli reference teaches Component B in a composition, it would have been obvious to and motivated one of ordinary skill in the art to have combined Martelli's Component B with Folkman's angiogenic protein to give synergistic results as claimed in claims 19, 23, 24 and 25.

Applicants have traversed the rejection. The ground for traversal is Martelli is the PCT equivalent of the '364 patent, and accordingly their disclosures are identical, the issues in 103 rejection are identical to the issues in the double patenting rejection. Applicants urge that accordingly the reasons given (at page 9 of remarks) why the present claims are not obvious from any disclosure of the '364 patent with Folkman are equally applicable to the rejection based the corresponding PCT application with Folkman. Applicants arguments are unpersuasive because Applicants have remarked at page 6 that in a 35, U.S.C. 103 rejection the examiner would never reject a claim for the administration of A and B based on a reference that only discloses the administration of A. Applicants should note that in 103 rejection the Examiner would combine with a second reference that discloses the administration of B.

Thus the combined references Martelli and Folkman would have resulted in the claimed invention which was *prima facie* obvious to make and use at the time it was made.

Claims 4, 10, 13 14 15, 16, 17, 18, 21 and 22 are rejected because they are dependent on rejected claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

No claims are allowed.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.  
December 5, 2003



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